

March 12, 2021

Marcia McNutt, Ph.D.

President, National Academy of Sciences, Engineering & Medicine

Chair, National Research Council

500 Fifth Street, NW

Washington, D.C. 20001

Re: IRIS Handbook Review Committee – Solicitation of Additional Panel Members

Dear Dr. McNutt:

The undersigned organizations have submitted comments to the National Research Council (NRC) panel reviewing the Integrated Risk Information System (IRIS) Handbook, which is scheduled to have its introductory public meeting in April. As expressed in the February 5<sup>th</sup> letter from the Arsenic Science Task Force, we too are concerned that the current panel may not have sufficient expertise to provide comprehensive recommendations to EPA concerning the IRIS Handbook. We request that the NRC expand the panel by at least three additional members who possess scientific expertise in disciplines unrepresented or under-represented in the current committee. Further, we request the NRC solicit nominees for those additional positions through an open and transparent process.

It is apparent that NRC was unsuccessful in its attempt to notify the affected scientific community of the pending committee and proposed committee membership. No comments were received by the NRC until months after the initial closed door meeting in October 2020. The 1997 FACA Amendments clearly require a public comment period regarding the provisional members of an advisory panel.<sup>1</sup> We are unaware of anyone who saw such a notice.

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<sup>1</sup> Federal Advisory Committee Act Amendments of 1997 (b) Requirements.--The requirements referred to in subsection (a) are as follows:

- (1) The Academy shall determine and provide public notice of the names and brief biographies of individuals that the Academy appoints or intends to appoint to serve on the committee. The Academy shall determine and provide a reasonable opportunity for the public to comment on such appointments before they are made or, if the Academy determines such prior comment is not practicable, in the period immediately following the appointments. The Academy shall make its best efforts to ensure that (A) no individual appointed to serve on the committee has a conflict of interest that is relevant to the functions to be performed,

We also agree with the Arsenic Science Task Force that the committee lacks expertise in key areas such as “medicine, metabolism, pathology, [and] chemistry.” ASTF letter at 1. In particular, we recommend that the National Academy of Science specifically examine whether the current panel members can probe, evaluate, and provide specific recommendations on best practices in each of the science issues that arise in each individual chapter of the Handbook (i.e., everything from scoping/problem formulation through development of toxicity values). It is critically important that the panel increase its expertise in understanding mode of action/mechanism of action.

Even a cursory review of the already submitted public comments reveals that there is a substantial number of comments to address in virtually every chapter. Moreover, the IRIS program provides a practical application of science by a government agency that has limited resources, time, and competing priorities. We believe experts that, either through their government service or through participating in past IRIS reviews, understand these constraints can provide important and applicable recommendations to improve the advice given to EPA.

There are many potential panelists that have substantial experience reviewing IRIS assessments over the last decade and more, who could lend substantial additional expertise to this panel. In effect, these panelists both with and without government experience have been critiquing the Handbook framework since 2011 and have substantial knowledge to share.

We recommend consideration of panelists who served on previous IRIS NRC panels, including the arsenic IRIS panel. In addition, Resha Putzrath, a recently retired toxicologist (former EPA and Navy) is but one example of someone who would be especially helpful to this panel. She currently serves on the NRC standing Committee on Toxicology and has more than a decade of experience reviewing, commenting on, and implementing IRIS assessments as a contractor for the Department of the Navy. In her work for the Navy, she has ably commented on many of the issues in the interagency review process that are addressed throughout the Handbook.

While we believe that additional panel members should be recruited in a publicly open and transparent manner, we have suggested a sample of scientists known to us, who could contribute immeasurably to a quality report. We also remind the NRC that its longstanding

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unless such conflict is promptly and publicly disclosed and the Academy determines that the conflict is unavoidable, (B) the committee membership is fairly balanced as determined by the Academy to be appropriate for the functions to be performed, and (C) the final report of the Academy will be the result of the Academy's independent judgment. The Academy shall require that individuals that the Academy appoints or intends to appoint to serve on the committee inform the Academy of the individual's conflicts of interest that are relevant to the functions to be performed.

See also <http://www.nasonline.org/about-nas/leadership/governing-documents/federal-advisory-committee.html>.

policy<sup>2</sup> also calls for a diversity of viewpoints, and not simply diversity in academia. Almost all our suggested panelists have substantial experience with using alternative hypotheses, alternative MOAs and addressing the underlying science – experience that is underrepresented in the current group (and frankly requires substantial additional attention in the Handbook). The inclusion of three additional members could address both missing expertise and missing viewpoint diversity.

We suggest consideration of the following persons:

James Bus, Exponent

Joyce Tusji, Exponent

Julie Goodman, Gradient

Lorenz Rhomberg, Gradient

Robinan Gentry, Ramboll US Consulting

Joseph Rodricks, Ramboll US Consulting

Vicki Dellarco, independent consultant

John Graham, Indiana University

George Gray, George Washington University

Penny Fenner-Crisp, Independent consultant

Rita Schoeny, independent consultant

Danielle Wikoff, Tox Strategies

Jay Goodman, Michigan State University (on NRC 2019 arsenic panel)

Barbara Beck, Gradient

Resha Putzrath (retired Navy toxicologist, currently member of standing NRC Committee on Toxicology)

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<sup>2</sup> POLICY ON COMMITTEE COMPOSITION AND BALANCE AND CONFLICTS OF INTEREST FOR COMMITTEES USED IN THE DEVELOPMENT OF REPORTS, National Academy of Sciences, National Academy of Engineering Institute of Medicine, National Research Council, Washington D.C., May 12, 2003; <https://www.nationalacademies.org/about/institutional-policies-and-procedures/conflict-of-interest-policies-and-procedures>.

We look forward to the NRC addressing this important omission to ensure that EPA will obtain robust and balanced advice to improve the Handbook to achieve the transparency and objective quality scientific assessments. We hope that NRC could add new panelists, as early as the next public meeting in April. For the IRIS program to reach “world-class” standards, NRC needs a fully vetted, balanced, and qualified panel in accordance with NRC policies and regulations. If you have further questions about this letter, please feel free to contact Kevin Bromberg or Jonathan Gledhill by email ([kevin.bromberg@gmail.com](mailto:kevin.bromberg@gmail.com); [jgledhill@policynavigation.com](mailto:jgledhill@policynavigation.com)) or phone (301-654-1578; 703-280-0430)

Respectfully Submitted,

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Policy Navigation Group

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American Composites Manufacturing Association  
American Forest & Paper Association  
Kitchen Cabinet Manufacturers Association

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